REMARKS

Status of Claims

Claims 1 – 73 were original in the application. Claims 1 – 34 and 63 – 73 have been withdrawn. Claim 42 has been currently amended. Claims 35 – 62 are submitted for examination on the merits.

Rejection Pursuant to 35 USC 112

The Examiner rejects claims 65 – 62 as failing to define the invention on the ground that the elements of the claims are defined in terms of functional or operational language. For example, "means for creating stress in tissue", the first element in claim 1 is rejected in that it "could be anything, including non-statutory subject matter."

As the Examiner is well aware the sixth paragraph of section 112 provides:

> "An element in a claim for a combination may be expressed as a **means or step for performing a specified function without the recital of structure, material, or acts in support thereof**, and **such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof**. "

Claim 35 is comprised to two elements, both of which are means elements. Pursuant to law, they are expressed as "a means . . . for performing a specified function without the recital of structure, material, or acts in support thereof." The Examiner is correct in asserting that claim 35 is defined in terms of functional or operational language. However, such a definition is expressly permitted by law.

The Examiner is not correct in asserting that the element "could be anything, including non-statutory subject matter." Section 112 expressly states that such

elements of a means claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. A means element could **not** be anything, including non-statutory subject matter, but must be what is disclosed as performing the defining function and equivalents thereto. The claims are in statutorily permitted form which is deemed clear as a matter of form according to law.

Claims 66 – 62 define various means in terms of other means or in terms of more limited defining functions performed by the means. The dependent claims thus are also in statutorily permitted form which is deemed clear as a matter of form according to law.

The Applicants respectfully direct the Examiner to the guidelines set forth in MPEP 2181 for examination of means claims. In *Donaldson,* the Federal Circuit stated:

> Per our holding, the "broadest reasonable interpretation" that an examiner may give means-plus-function language is that statutorily mandated in paragraph six. Accordingly, **the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination**.

For example, the means for creating stress in tissue in claim 35 is described in the specification as:

> [0014] This disclosure describes the process of tissue electroforming and how shape changes in cartilage can be produced by the application of direct current (DC). The dependence of shape change on voltage, application time and electrode composition is explained. In the illustrated embodiment, the investigation uses ex vivo porcine septal cartilage grafts and electromechanical cartilage deformation focused on development of a new surgical technique. **To illustrate the invention uniform flat porcine nasal septal cartilage specimens were mechanically deformed between two semicircular aluminum and gold electrodes.** DC current was applied to establish charge separation and electrical streaming potential. Voltage (0-6 V) and application time (0-5 minutes) were varied. Shape change was measured, and shape retention was calculated using analytic representation. The effect of the direction of applied current on shape change was evaluated by switching the polarities of electrodes and using parameters of 0 to 5.5 V and 5 minutes. Temperature

during reshaping was monitored with a thermocouple, **internal stress was monitored with a load cell**, tissue impedance was monitored with a volt--and ampermeter and surface features were evaluated using light microscopy. Reshaped specimen demonstrated mechanical stability similar to native cartilage tissue. Shape retention and stress relaxation strongly correlated with increasing voltage and application time. Only a small current (<0.1 A) through the tissue was measured. Temperature change was less than 2.degree. C. during electroforming, suggesting that electroforming likely results from some nonthermal mechanisms. Tissue impedance change accompanied with stress relaxation likely confirms electro-mechanical mechanism of reshaping. Surface features indicated that electrodeposition may occur depending on electrode material and magnitude of the applied voltage.

[0018] **The step of creating stress in the tissue comprises in one embodiment the step of mechanically applying force to the tissue to create external stresses applied to the tissue. In another embodiment the step of creating stress in the tissue comprises changing material parameters of the tissue to create internal stresses in the tissue by causing a current to flow in the tissue.**

[0022] The step of creating stress in the tissue comprises creating tension, compression shear or a combination thereof in the tissue.

[0024] The step of creating stress in the tissue and causing a current to flow in the tissue comprises the step of contacting the tissue with a pair of curved electrodes, which may include contact with a sharply angled electrode or a smoothly angled electrode.

[0037] FIGS. 8A and 8B are graphs of resistance and stress as a function of time at different electroforming voltages.

[0054] It is to be expressly understood that **the mechanical means for applying the external stress may be comprised of any type of conductive element, such as metals, conductive polymers or conductive gels or electrolytic solutions carried on rigid or resilient carriers**. Jigs 18, 20 may have any geometry that is desired including curved, flat, sharply or smoothly angled. In addition to have surface contact electrodes such as shown in FIG. 1, the electrodes may be one or more conductive needles which provide a point pressure contact or actual penetration into the tissue. In the case of one or both electrodes of the pair being in needle form, an array of microneedles may be employed and applied with varying voltages, so that like an ink jet printer, any two dimensional pattern of voltages on any shaped surface could be provided. In addition, if desired, a plurality of needle electrodes of one polarity may be provided mixed or arranged in a complex array of needles of the opposite polarity, or in a plurality of isolated through-holes defined in a conductive surface provided with the opposite polarity.

[0076] **In a surgical context as shown in FIG. 10 an instrument can be devised in which the two electrodes are brought to bear on the tissue site either in the form of pressure electrodes or penetrating electrodes or both.** The electrode pair 68 may, for example, be mounted on and electrically isolated on a pair of tongs 66 coupled to a current or voltage source 16 and comprise a mold. The surgeon then brings the instrument 66 into contact with at least one of the molded surfaces of the tissue to be reshaped, **creates the stress**, and applies an effective voltage for effective time to obtain the molded shape desired. The electrodes 68 may be subdivided into multiple pieces so that there is an array of small plate electrodes or a needle array as described above.

[0077] For example, where only one surface of the cartilage or tissue is accessible, **a molded electrode surface is brought to bear against the accessible tissue surface to provide pressure or stress in the tissue**, namely to indent the surface, and one or more needles are inserted to effectively form the opposing electrode across the indented tissue layer to be reshaped. The tissue will tend to permanently bend to conform to the molded electrode.

[0082] FIGS. 15a and 15b show a bottom plan view looking upwardly of the cartilage anatomy 100 in a typical human nose 98. FIG. 15a shows the beginning anatomy of the medial and lateral cura, where the tip of the nose is bulbous or rounded in section due to the underlying cura shape. FIG. 15b shows the same nose 98 after the medial and lateral cura of cartilage 100 has been more acutely electroformed to give a pointed nose tip shape. This is accomplished by means of a pair of shaped jigs 102 and 104 carrying electrodes or acting as electrodes and coupled to voltage source 72. Incisions are made into the base of nose 98 and jigs 102 and 104 are slide into place on each side of the cura. **Jigs 102 and 104 are directly or indirectly squeezed together to apply stress or compression to the cura as current or voltage is applied to jigs 102 and 104.**

Stress, stress relaxation and its characterization is replete throughout the specification and leave no doubt what disclosed elements comprise the "means for creating stress in tissue." Similarly, each means in claims 35 – 62 could be documented by reference to the specification. The applicant requests the Examiner to particularly point out where such disclosure for any element cannot be found.

The Examiner also appears to question whether an operable combination is claimed. The Applicants respectfully disagree that the combination of claim 35 is not

operable. Claim 35 clearly claims an operable combination of elements which have in fact been used to actually electroform tissue. There is a means for creating stress in the tissue combined with a means for causing a current to flow in the tissue while the created stress is present to change shape of the tissue or material parameters of the tissue. This could be viewed as a definition of electroforming. Nothing further is required and the specification provides actual disclosure of where cartilage is electroformed.

The applicants describe in detail the biophysical behavior of cartilage during electroforming by showing the degree of shape change in actual porcine nasal septal cartilage grafts using the combination of claim 35. In particular, they evaluate the dependence of shape change on the magnitude and polarity of the applied DC voltage and application time as well as monitoring tissue temperature, internal stress and impedance and electrode deposition during this reshaping process. Characterizing the effects of applied voltage and the duration of treatment is an important step in understanding the physical processes responsible for electroforming and providing insight into how this procedure can be optimized.

Applicant respectfully requests advancement of the claims to allowance.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 31, 2006 by JoAnn Breen.

Signature

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